



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/536,551 03/28/00 MORRE

D 8951-124-999

020583  
PENNIE AND EDMONDS  
1155 AVENUE OF THE AMERICAS  
NEW YORK NY 10036-2711

HM22/0914

EXAMINER

WELLS, J.  
ART UNIT PAPER NUMBER

1619  
DATE MAILED:

09/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.

09/536,551

Applicant(s)

MORRE ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 1-11 and 25-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.                      6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-54 are pending. Claims 1-11 and 25-54 are withdrawn from consideration, as they are drawn to non-elected subject matter.

#### ***Election/Restrictions***

Applicant's election without traverse of Group II in Paper No. 5 is acknowledged.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12, 14, 17-20, 22 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The phrase “incubating in a reaction comprising. . .AR-NOX” in claims 12, 17, 20 and 24 (lines 2-3) is vague and indefinite, as it is not clear how one incubates in a reaction and further how a reaction can comprise something.

(ii) The phrase “positive control” in claim 14 (line 2) is vague and indefinite, as it is not clear what these phrase means.

(iii) The phrase “capable of” in claim 17 (line 3) and claim 18 (line 1) is vague and indefinite, as it has been held that the recitation that an element is “capable of” performing a function is not a positive limitation but only requires the ability to so perform that function. It does not constitute a limitation in any patentable sense. *In re Hutchinson*, 69 USPQ 138.

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(iv) The phrases "test agent" and "test compound" in claims 12, 17, 20 and 24 (lines 3 and 7) are vague and indefinite, as these phrases are not defined by the specification and one of ordinary skill in the art would not be appraised of them.

(v) Claims 19 and 22 are vague and indefinite, as it is not clear what the detection of cytochrome c and ascorbate radical are being compared to.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morre et al. (5,569,673) in view of Morre et al. (BioFactors 9).

Morre et al. teach a method for determining neoplasia in a mammalian host comprising detecting the presence of an NADH oxidase associated with neoplastic cells as compared to a different NADH oxidase associated with normal cells, wherein the detection is by means of an immunoassay. In a first assay is NADH oxidase and an NADH oxidase inhibitor, which discriminates between NADH oxidase from normal cells and NADH oxidase from neoplastic cells, wherein quinone-like structures are disclosed as inhibitors. The inhibition of NADH oxidase is then determined with an ascorbate free radical as a reactant, wherein the reduction of

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ascorbate free radical is measured at 265nm by a spectrophotometer in intact cells suspended in a buffer medium containing ascorbate. It is further disclosed that a) detection of NADH oxidase may be achieved by employing antibodies which may be conjugated with labels such as radioisotopes, enzymes, fluorescers, and chemiluminescers and b) in assaying for NADH oxidase activity one may measure the rate of disappearance of NADH, the appearance of NAD<sup>+</sup>, or the rate of appearance or disappearance of another reaction product or reactant. Morre et al. fail to teach screening within a cell, cytochrome c, superoxide dimutase, and a substrate undergoing disulfide-thiol interchange activity.

Morre et al. teach a multifunctional NADH oxidase with protein disulfide thiol interchange activity associated with the plasma membrane. It is disclosed that hyperactivity or interruption of the electron transfer by NADH oxidase from NADPH or hydroquinone to molecular oxygen or protein thiols can result in the production of superoxides. This was further tested by using cultured cells and UV light, which is used to induce superoxide generation, to perturbate electron flow. It was found that the production of superoxide resulted in the reduction of cytochrome c and that the UV induced increase in cytochrome c reduction was inhibited by superoxide dimutase, implicating superoxide as the source of reduction of cytochrome c. It is further disclosed that the superoxide dimutase inhibitable reduction of cytochrome c is assumed to be due to the cell surface NADH oxidase.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Morre et al. ('810) using the teachings of Morre et al. (BioFactors 9) and obtain a method for screening for agents that sequester AR-NOX comprising cytochrome c or ascorbate radical or NAD<sup>+</sup> or disulfide-thiol interchange activity

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as detections means and superoxide dismutase as a substrate capable of generating reactive oxygen species because a) both references teach NADH oxidase assays for determination of cellular activity; b) Morre et al. ('810) teach that inhibitors may vary as to structure in relation to the particular binding site target, therefore allowing a variety of compounds to act as detectors.

The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

#### *Prior Art*

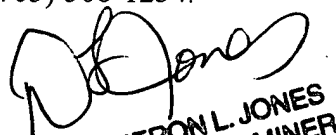
The prior art made of record and not specifically relied upon in any rejections cited above is either 1) considered cumulative to the prior art that was cited in a rejection or is 2) considered pertinent to the applicant's disclosure and shows the state of the art in its field but is not determined by the Examiner to read upon the invention currently being prosecuted in this application.

#### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana L Dudash can be reached on (703) 308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.



DAMERON L. JONES  
PRIMARY EXAMINER

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lqw

August 7, 2001